Remarks/Arguments:

Claims 1 - 16 are presently pending. All pending claims stand rejected. Applicants herein amend claims 1, 14 and 15 to indicate that the related materials are physical analytical materials. Support for this amendment can be found throughout the specification as originally filed. For example, see Page 8, lines 9 - 20. No new matter is added. Applicants respectfully request reconsideration based on the above amendments and the following remarks.

Section 2 of the Office Action recites that "claims 1 - 16 are rejected under 35 U.S.C. §112, second paragraph as being indefinite." The Office Action indicates that the phrase "providing a pharmaceutical product supplier" is unclear as to the entity distributing "said disease management related materials." The Office Action recites that "as the claim is presently written, the entity could be a pharmaceutical company or a pharmacy" and "depending on the interpretation of the reader, the claimed invention could be directed to a pharmaceutical manufacturer implementing a mandatory disease management regime to accompany the distribution of a drug or, alternatively, the invention could be directed to a pharmacist simply distributing guidelines to a patient as to the best mode of treatment." It is Applicants' intention that the phrase "providing a pharmaceutical product supplier" covers any entity that distributes pharmaceuticals, including pharmaceutical manufacturers and pharmacists. In addition, claim 1, as amended, recites that the related materials are related physical analytical materials and, thus, the claimed invention would not be interpreted as directed to the implementation of a mandatory disease management regime or the distribution of guidelines to a patient as to the best mode of treatment. Accordingly, Applicants contend that the phrase "providing a pharmaceutical product supplier" is definite.

Additionally, the Office Action indicates that the phrase "means of communication between said doctor, a patient, and said pharmaceutical supplier" is unclear as to whether the applicants intend to enable three-way communication among the respective parties, as would be the case with a network environment, or if two-way communication between any two of the respective parties would meet this requirement. Applicants herein amend claim 1 to clarify that the communication is "means of communication between said doctor and the patient," thereby rendering this portion of the claim definite.

Accordingly, for the reasons discussed above, Applicants contend that claim 1 is definite and respectfully request that the rejection of claim 1 under 35 U.S.C. §112 be withdrawn.

The Office Action recites that "claims 2- 13 when analyzed in the same manner described above with respect to claim 1, are also rejected under 35 U.S.C. 112 as being indefinite." As Applicants have explained above, claim 1 is definite. Accordingly, claims 2 -13 are likewise definite. Therefore, applicants respectfully request that the rejection of claims 2 - 13 as being indefinite be withdrawn.

The Office Action recites that "claims 14 and 15 are rejected under 35 U.S.C. 112 as being indefinite." Specifically, the Office Action indicates that the limitation "providing a pharmaceutical supplier" renders the claim indefinite by the same analysis as applied to claim 1 above. Applicants have herein amended claims 14 and 15 in a manner similar to claim 1 and therefore contend that claims 14 and 15 are definite. Accordingly, Applicants request that the rejection of claims 14 and 15 as being indefinite be withdrawn.

The Office Action indicates that claim 14 is indefinite for providing insufficient basis for "said disease state management program." Applicants herein amend claim 14 to remove the term "state" from this phrase. Thus, the phrase now reads "the disease management program." Antecedent basis for this phrase is found in the first element of claim 14, line 3. Accordingly, Applicants contend that claim 14 is definite and respectfully request that the rejection of claim 14 as being indefinite be withdrawn.

The Office Action recites that claim 16, by virtue of its dependence on claim 15, and when analyzed in the same manner described with respect to claim 15, also fails to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention. As indicated above, Applicants contend that claim 15 is definite. Accordingly, Applicants contend that claim 16 is likewise definite and therefore respectfully request that the rejection of claim 16 as being indefinite be withdrawn.

The Office Action recites that "claims 1-4, 6-11, and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Portwood et al. (U.S. Patent No. 6,305,377) in view of Akers et al. (U.S. Patent No. 6,112,182)." Claim 1 includes at least one feature that is neither

disclosed nor suggested by Portwood in view of Akers. Claim 1 is directed to a method for distributing pharmaceutical products that includes the following steps:

> developing a disease management program and related physical analytical materials having specific relevance to a counterpart pharmaceutical product to be distributed to patients in conjunction with said counterpart pharmaceutical product, the related physical analytical materials to be used by a patient during the disease management program and results obtained from the physical analytical materials to be communicated to a doctor;
>
> providing a pharmaceutical product supplier to supply said disease management program related physical analytical materials directly to the patient in conjunction with said counterpart pharmaceutical product when said patient fills a prescription;
>
> communicating to a doctor said disease management program and said related physical analytical materials and said relevance of said program and said materials to said counterpart pharmaceutical product; and
>
> providing means of communication between said doctor and a patient for whom said doctor has prescribed said disease management program and its counterpart drug.

This means that pharmaceutical products in accordance with this aspect of the claimed invention are distributed by developing a disease management program and related physical analytical materials having specific relevance to a counterpart pharmaceutical product for distribution. In addition, a pharmaceutical product supplier is provided to supply the disease management program related physical analytical materials directly to the patient in conjunction with the counterpart pharmaceutical product when the patient fills the prescription. The disease management program and the related physical analytical materials are communicated to a doctor. Further, means of communication are provided between the doctor and the patient.

Neither Portwood nor Akers discloses, teaches or suggests the development of a disease management program and related physical analytical materials having specific relevance to a counterpart pharmaceutical product to be distributed to patients in conjunction with the counterpart pharmaceutical product where the related physical analytical materials to be used by the patient during the disease management program and the results from the physical analytical materials are to be communicated to a doctor. This enables the program to be

specific for each pharmaceutical product. For example, where diabetes is the disease involved, self-diagnostic kits for at-home blood glucose analysis may be a part of the physical analytical materials for the management program. As another example, where the disease is hypertension, blood pressure measurement equipment may be supplied. Further, the materials may include such things as surrogate marker tests for acute or chronic conditions. See Page 8, lines 1-20 of the application as originally filed. Portwood and Akers fail to disclose, teach or suggest the distribution of such physical analytical materials in conjunction with a pharmaceutical product.

Accordingly, for the reasons discussed above, Applicants contend that claim 1 is allowable over Portwood and Akers and, therefore, respectfully request that the rejection of claim 1 be withdrawn.

Claims 14 and 15, while not identical to claim 1, include features similar to claim 1. Accordingly, Applicants contend that claims 14 and 15 are allowable for the same reasons discussed above that claim 1 is allowable. Accordingly, Applicants respectfully request that the rejections of claims 14 and 15 be withdrawn.

Claims 2-4, 6-11, and 16 each depend from either independent claim 1 or independent claim 15 and include all of the limitations of the independent claim from which they depend. Accordingly, Applicants contend that claims 2-4, 6-11, and 16 are allowable for the same reasons that claims 1 and 15 are allowable and, therefore, Applicants respectfully request that the rejections of claims 2-4, 6-11, and 16 be withdrawn.

Section 4 of the Office Action recites that "claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Portwood and Akers... and further in view of Baruch, et al. (U.S. Patent Application Publication No. 2002/0077849)." Claims 12 and 13 ultimately depend from claim 1 and include all of the features and limitations of claim 1. The feature that was found to be lacking in Portwood and Akers with reference to claim 1 is not found in Baruch. Thus, Baruch fails to make up for the deficiencies for Portwood and Akers. Accordingly, Applicants contend that claims 12 and 13 are allowable and, therefore, respectfully request withdrawal of the rejection.

In view of the amendments and remarks set forth above, Applicants respectfully submit that claims 1 through 16 are in condition for allowance and early notification to that effect is earnestly solicited.

Respectfully submitted,

Jonathan H. Spadt, Reg. No. 45,122
Stephen J. Weed, Reg. No. 45,200
Attorneys for Applicants

JHS/SJW/mhs

Dated: March 30, 2006

☒ P.O. Box 980
Valley Forge, PA 19482
(610) 407-0700

The Director is hereby authorized to charge or credit Deposit Account No. **18-0350** for any additional fees, or any underpayment or credit for overpayment in connection herewith.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, with sufficient postage, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on: March 30, 2006

Mary H. Stephenson

Mary H. Stephenson